

### REMARKS

Claims 27-32 are pending. Claims 27 and 28 are amended. Support for claim amendments can be found at page 9, lines 22-29 and page 14, lines 1-6; lines 26-28. A version showing changes made is attached for the Examiner's convenience. An appendix of the currently pending claims is also attached for the Examiner's convenience.

### Drawings

The drawings are objected to under 37 C.F.R. § 1.83(a). In response, Applicants are submitting herein a new figure 6. The waste reservoir in combination with the rotor is now depicted in figure 6. Other embodiments are contemplated as disclosed in the specification. Support for amendment of specification and drawings is found at page 14, lines 19-25. No new matter is introduced by way of this amendment. Figure 6 depicts a cross section of a centrifuge with a waste reservoir connected to the bottom of the centrifuge.

### Claim rejections based under 35 U.S.C. § 102

Claims 27, 28 and 30-32 are rejected under 35 U.S.C. § 102(b) as being anticipated by American Hospital Supply (GB 1 241 539). Applicants respectfully traverse.

Claims 27 and 28, from which all other claims depend, are directed to a centrifuge which includes a rotor which holds in a fixed position at least one reaction vessel tilted away from the axis of rotation.

In contrast, American Hospital Supply discloses a centrifuge and methods for treating and washing blood cells. The invention calls for washing fluids to be forcefully introduced into each tube at the open end thereof as such tube is traveling rapidly about an axis of centrifugation. The invention also calls for a manifold assembly which assures uniform distribution of fluid and which discharges such fluid into the tubes with sufficient velocity to assure complete dispersion

of cells. American Hospital Supply does not teach or suggest a centrifuge with a rotor which holds in a fixed position at least one reaction vessel tilted away from the axis of rotation, which is an element of amended claims 27 and 28, from which all other claims depend.

The law is well established that in order to anticipate a claim, the prior art must disclose "each and every element" of the claimed invention *SSIH Equipment S.A. v. U.S. Inc. Int'l. Trade Commission*, 218 USPQ 678, 688 (Fed. Cir. 1983). As stated by the Federal Circuit in *In re Bond*, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990), "[f]or a prior art reference to anticipate in terms of 35 U.S.C. § 102, every element of the claimed invention must be identically shown in a single reference." (Emphasis added). See also *Glaverbel Societe Anonyme v. Northlake Marketing & Supply, Inc.*, 33 USPQ2d 1496 (Fed. Cir. 1995).

Here each and every element is not present in the prior art. As stated above, American Hospital Supply does not teach or suggest a centrifuge comprising a rotor which holds in a fixed position at least one reaction vessel tilted away from the axis of rotation. Therefore, American Hospital Supply does not anticipate the claims of the present invention.

The Examiner points to page 2, lines 90-96 and Figure 9 of American Hospital Supply as evidence of anticipation for tubes tilted away from the axis of rotation. See Office Action page 3. However, nowhere in American Hospital Supply, including the section cited by the Examiner, is there a teaching or suggestion of a rotor which holds in a fixed position at least one reaction vessel tilted away from the axis of rotation. The section cited by the Examiner discusses an inward displacement of the tubes to permit the removable head to be utilized as a tube storage rack when the head is removed from the well. See American Hospital Supply at page 2, lines 96-105. In American Hospital Supply, the recesses of the head assembly do not hold the tubes in a fixed position tilted away from the axis of rotation as claimed in the present invention.

Accordingly, the rejection is improper and Applicants respectfully request the withdrawal of the rejection.

Claims 27 and 30-32 are rejected under 35 U.S.C § 102(b) as being anticipated by Genese et al. (U.S. 3,712,535).

Again, claim 27 is directed to a centrifuge which includes a rotor which holds in a fixed position at least one reaction vessel tilted away from the axis of rotation.

In contrast, Genese et al. discloses an apparatus for automatically performing a series of operations on a blood sample contained in a vial. Genese discloses a centrifuge with a carrier which includes individual receptacles for receiving individual vials by which the lower portion of the carrier is received in the four walls defining an trunnion. Genese et al. does not teach or suggest a rotor which holds in a fixed position at least one reaction vessel tilted away from the axis of rotation.

As stated above, in order to anticipate a claim, the prior art must disclose "each and every element" of the claimed invention *SSIH Equipment S.A.v. U.S. Inc. Int'l. Trade Commission*, 218 USPQ 678, 688 (Fed. Cir. 1983). As stated by the Federal Circuit in *In re Bond*, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990), "[f]or a prior art reference to anticipate in terms of 35 U.S.C. § 102, every element of the claimed invention must be identically shown in a single reference." (Emphasis added). See also *Glaverbel Societe Anonyme v. Northlake Marketing & Supply, Inc.*, 33 USPQ2d 1496 (Fed. Cir. 1995).

Here each and every element is not present in the prior art. As stated above, Genese does not teach or suggest a centrifuge with a rotor which holds in a fixed position at least one reaction vessel tilted away from the axis of rotation. Therefore, Genese does not anticipate the claims of the present invention. The Examiner cites to page 6, lines 28-49 of Genese et al. as evidence of

anticipation. This section of Genese cited by the Examiner discusses how when the magnetic insert of the trunnion which is a short distance from the pole ring comes into contact with the pole ring upon actuation of the coil, the trunnion, which holds the carrier and the vials, is disposed at a negative angle. The carrier or holder of Genese does not hold at least one reaction vessel or at least one microtiter plate at a fixed position tilted away from the axis of rotation as claimed in the present invention. Rather, the holder of Genese moves relative to the movement of the trunnion when the carrier is mounted in the trunnion based on whether or not the coil is energized or de-energized. See Genese at column 5, lines 45-69; and column 6, lines 16-55.

Accordingly, the rejection is improper and Applicants respectfully request the withdrawal of the rejection.

**Claim rejections based under 35 U.S.C. § 103**

Claims 28 and 30-32 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Genese et al. (U.S. 3,712,525) in view of American Hospital Supply (GB 1 241 539).

The disclosures of both Genese et al. and American Hospital Supply are discussed above and are incorporated at this point by reference.

In contrast, the claims of the present invention provides for an apparatus with a centrifuge including a rotor which holds in a fixed position at least one reaction vessel titled away from the axis of rotation. Claim 28 of the present invention also provides for a waste reservoir connected with a tube to the centrifuge to hold liquids expelled from the reaction vessels.

As the Examiner is aware, to establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation

of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The Examiner states that it would have been obvious to one of ordinary skill in the art to employ a tube and vessel system of American Hospital Supply with the drain port of Genese for the known and expected result of providing a means known in the art for collecting waste materials. Applicants respectfully traverse.

As a preliminary matter, neither reference alone or in combination teaches or suggests a rotor which holds in a fixed position at least one reaction vessel tilted away from the axis of rotation. Therefore the requirement that the prior art reference (or references when combined) must teach or suggest all the claim limitations has not been met. For the reasons set forth above, the rejection is improper and the applicants respectfully request the withdrawal of the rejection.

In addition, in the instant case there is lacking any suggestion or motivation to modify the references or combine reference teachings. The Examiner cites to the expected result of providing a means known in the art for collecting waste materials as the motivation to combine references to reach the claims of the present invention. See Office Action at page 4.

The Examiner refers to the windage bowl(40) of Genese as being a container. See Office Action at page 4. Applicants submit that the windage bowl is not a waste reservoir but can be more aptly described as a means to reduce the air friction generated from the high speed rotation of the rotor which sits in the windage bowl. See figure 2; and Webster's 3<sup>rd</sup> New International Dictionary, unabridged, for the definition of "windage" as the disturbance of the air caused by a passing object; air friction against a rapidly moving especially rotating object. Applicants have

submitted exhibit A, which is a copy of the definition of "windage" from Webster's 3<sup>rd</sup> New International Dictionary, unabridged for the Examiner's convenience. The windage bowl of Genese is not designed to collect waste and because a windage bowl is not a collector, one skilled in the art would not have been motivated to combine a windage bowl with the vessel system of American Hospital Supply as suggested by the Examiner for collecting waste materials.

In addition, Applicants note that in determining the differences between the prior art and the claims, the question under 35 U.S.C 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. *Stratoflex, Inc. v. Aerowhip Corp.*, 713 F. 2d 782, 218 USPQ 698 (Fed. Cir. 1983). Here it is claim 28 as a whole that must be considered in determining obviousness. Applicants note that a centrifuge with a rotor which holds reaction vessels at a fixed position titled away from the axis of rotation is an element of all the claims of the present invention and must be considered in determining obviousness.

In addition, Applicants submit that the Examiner's statement of the motivation provided by American Hospital Supply of using a drain tube and a waste vessel, does not provide the specific guidance required to provide motivation to modify or combine the references of American Hospital Supply and Genese to reach the claims of the present invention. To this end, Applicants remind the Examiner that it is improper to use an obvious to try approach or to cite to only general guidance as to the particular form of the claimed invention or how to achieve it. See *In re O'Farrell*, 853 F. 2d 894,903, 7 USPQ2d 1673,1681 (Fed. Cir. 1988).

In summary, the claims as a whole have not been considered, which includes a rotor which holds in a fixed position at least one reaction vessel titled away from the axis of rotation.

In addition, neither reference alone or in combination teaches or suggests all claim limitations and there is lacking any teaching or suggestion to modify or combine reference teachings. For all of the forgoing reasons, the rejection is improper and Applicants respectfully request the withdrawal of the rejection.

Claims 29/27 and 29/28 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Tamai (JP 64-83153) in view of American Hospital Supply (GB 1 241 539).

The disclosure of American Hospital Supply has been discussed above and is incorporated at this point by reference.

Tamai was written in Japanese and only the abstract has been translated into English. Referring to the abstract and Figures 1 and 2, Applicants note that Tamai discloses a rotor which holds multiple microplates and has a channel for collecting waste when in use. The apparatus in Tamai is designed to allow for automation of an entire analytical process, so that the analyst does not have to handle potentially contaminated equipment, thereby reducing the risk of contagion. In operation, the apparatus of Tamai appears to operate as follows: as the rotor rotates, a cleansing solution is sprayed across the surface of the rotor and across the microplates. *Tamai*, abstract. The cleansing liquid and contents of the microplate wells are expelled from the reaction wells and travel to the waste channel under the influence of the centrifugal force caused by the rotation of the rotor. *Id.* Tamia does not teach or suggest a rotor which holds reaction vessels in a fixed position tilted away from the axis of rotation.

In contrast the present invention, as amended, provides a centrifuge with a rotor which holds reaction vessels in a fixed position tilted away from the axis of rotation. *See* Claim 27. The apparatus also provides for a waste reservoir, which is connected to the bottom of the centrifuge (claim 27) or connected by a tube to the centrifuge (claim 28), designed to hold the

liquids that are expelled from the reaction vessels. *Id.* Additionally, the rotor is designed to hold microtiter plates (claim29) or at least one reaction vessel (claim27) in a fixed position titled away from the axis of rotation.

As stated above, to establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The Examiner states that it would have been obvious to one of ordinary skill in the art to modify the holder of the primary reference so as to allow the vessels to tilt outward for the known and expected result of ensuring the emptying of the wells as is taught by American Hospital Supply and is required by the primary reference of Tamai. Applicants respectfully traverse.

Nowhere in either reference is there a teaching or suggestion of a rotor which holds reaction vessels in a fixed position titled away from the axis of rotation. The Examiner cites to page 4, lines 30-40 of American Hospital Supply as disclosing vessels titled outward but this section of American Hospital Supply discusses the outward pivoting of the tubes upon lifting of the hood assembly, there is no discussion of holding the tubes in a fixed position titled away from the axis of rotation. As noted by the Examiner, Tamai does not teach or suggest plates held in a fixed position titled away from the axis of rotation of the rotor. See office action at page 4.



Therefore the requirement that the prior art reference (or references when combined) must teach or suggest all the claim limitations has not been met.

In addition, in the instant case there is lacking any suggestion or motivation to modify the references or combine reference teachings. As noted briefly above, the Examiner states that it would have been obvious to one skilled in the art to modify the holder of Tamai so as to allow the vessels to tilt outward for the known and expected result of ensuring the emptying of the wells. Applicants respectfully traverse.

Applicants submit that this is a legally incorrect determination of motivation. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). There is no suggestion in either reference of modifying or combining the references to reach the claims of the present invention. That is, while American Hospital Supply et al. describes tubes pivoting outward for automatic decanting, there is nothing cited to in either reference that teaches or suggests the use of a rotor which holds at least one reaction vessel or microtiter plate in a fixed position tilted away from the axis of rotation. In addition, as stated previously, there is nothing taught or suggested by Tamai regarding the desirability of using a rotor which holds reaction vessels in a fixed position tilted away from the axis of rotation.

There is no suggestion whatsoever in any of the references for modifying the holder of Tamai or to combine the references to reach the claims of the present invention. To this end, Applicants remind the Examiner that it is improper to use an obvious to try approach or to cite to only general guidance as to the particular form of the claimed invention or how to achieve it. See *In re O'Farrell*, 853 F.2d 894,903, 7 USPQ2d 1673,1681 (Fed. Cir. 1988). For the foregoing

reasons, the rejection is improper and the Applicants respectfully request the withdrawal of the rejection.

Claim 29/27 is rejected under 35 U.S.C § 103(a) as being unpatentable over Tamai (JP 64-83153) in view of Genese et al. (3,712,525).

The disclosures of Tamai and Genese are discussed above and incorporated at this point by reference.

The Examiner states that it would have been obvious to one of ordinary skill in the art to modify the holder of Tamai so as to allow the vessels to tilt outward for the known and expected result of ensuring the emptying of the wells. The Examiner further states that it is known in the art to decant a vessel in a centrifuge device using a negative tilt and then references column 9, lines 28-47 of Genese. Applicants respectfully traverse.

As stated above, to establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

As stated previously, neither Genese or Tamai alone or in combination teaches or suggests a rotor which holds at least one reaction vessel (claim 27) or at least one microtiter plate (claim 29) in a fixed position tilted away from the axis of rotation. Therefore, the requirement that the prior art reference (or references when combined) must teach or suggest all

the claim limitations has not been met.

In addition, there is lacking any motivation to modify or combine reference teachings to reach the claims of the present invention. As noted briefly above, the Examiner states that it would have been obvious to modify the holder of Tamai so as to allow the vessels to tilt outward for the known and expected result of ensuring the emptying of the wells. The Examiner further states that it is known in the art to decant a vessel in a centrifuge device using a negative tilt and then references column 9, lines 28-47 of Genese. However, the section cited by the Examiner discusses the coombs injection assembly and is totally unrelated to decanting of tubes. In addition, as stated previously, the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F 2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). There is nothing cited to in either reference that would have motivated one skilled in the art to modify the holders of Tamai or to combine references to reach the claims of the present invention which includes a rotor which holds at least one reaction vessel or microtiter plate in a fixed position tilted away from the axis of rotation. Accordingly the rejection is improper and Applicants respectfully request the withdrawal of the rejection.

Claim 29/28 is rejected under 35 U.S.C § 103(a) as being unpatentable over Tamai (JP 64-83153) in view of Genese et al. (3,712,535) and American Hospital Supply (GB 1 241 539).

The disclosures of Tamai, Genese and American Hospital Supply have been discussed above and are incorporated at this point by reference.

The Examiner states that it would have been obvious to one of ordinary skill in the art to employ a tube and vessel system of American Hospital Supply with the drain port of the primary reference (which in this case is Tamai, but Tamai does not disclose a drain port so presumably

the Examiner is referring not to Tamai but to Genese which does disclose a drain port but is a secondary reference) for the known and expected result of providing a means known in the art for collecting waste materials. Either way, Applicants respectfully traverse.

As stated above, to establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Initially, Applicants note as previously stated, none of the references alone or in combination teach or suggest a rotor which holds in a fixed position at least one reaction vessel tilted away from the axis of rotation. Although Genese discloses a catch bottle at the bottom of the windage bowl and although American Hospital Supply discloses a waste receiver and a drain tube, neither reference alone or in combination teaches or suggests a rotor which holds at least one reaction vessel in a fixed position tilted away from the axis of rotation, which is an element of all the claims of the present invention. Therefore, the requirement that the prior art reference (or references when combined) must teach or suggest all the claim limitations has not been met.

In addition, as previously noted it is the claim as a whole that must be considered in determining obviousness. *Stratoflex, Inc. v. Aerowhip Corp.*, 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983). Here it is claim 28 as a whole that must be considered in determining obviousness and a rotor which holds reaction vessels at a fixed position tilted away from the axis of rotation is

an element of all the claims of the present invention and must be considered in determining obviousness.

In addition, there is lacking any teaching or suggestion to modify the cited references or combine reference teachings to reach the claims of the present invention. As noted previously, the windage bowl of Genese is not designed to collect waste and because a windage bowl is not a collector, one skilled in the art would not have been motivated to combine a windage bowl with the vessel system of American Hospital Supply as suggested by the Examiner for collecting waste materials. In addition, the Examiner cites to the drain port of the primary reference, which is Tamai but although Tamai discloses a discharge channel, Tamai does not teach or suggest a drain port.

In addition, Applicants submit that the Examiner's statement of the motivation provided by American Hospital Supply of using a drain tube and a waste vessel, does not provide the specific guidance required to provide motivation to modify or combine the references of Tamai, American Hospital Supply, and Genese to reach the claims of the present invention. To this end, Applicants remind the Examiner that it is improper to use an obvious to try approach or to cite to only general guidance as to the particular form of the claimed invention or how to achieve it. See *In re O'Farrell*, 853 F. 2d 894,903, 7 USPQ2d 1673,1681 (Fed. Cir. 1988).

In summary, the claims as a whole have not been considered, which includes a rotor which holds in a fixed position at least one reaction vessel tilted away from the axis of rotation. In addition, neither reference alone or in combination teaches or suggests all claim limitations. And finally, there is lacking any teaching or suggestion to modify or combine reference teachings. For all of the forgoing reasons, the rejection is improper and Applicants respectfully request the withdrawal of the rejection.

## CONCLUSION

Applicants respectfully submit that the claims are now in condition for allowance and early notification to that effect is respectfully requested. If the Examiner feels there are further unresolved issues, the Examiner is respectfully requested to phone the undersigned at (415) 781-1989.

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Filed under 37 C.F.R. § 1.34(a)

**VERSION SHOWING CHANGES MADE**

**IN THE CLAIMS**

27. (thrice Amended) An apparatus comprising:

a) a centrifuge comprising a rotor [designed to hold reaction vessels at a tilt away from the] rotatable about an axis of rotation which holds in a fixed position at least one reaction vessel tilted away from said axis of rotation; and

b) a waste reservoir connected to the bottom of said centrifuge to hold liquids expelled from said reaction vessels.

28. (twice amended) An apparatus comprising:

a) a centrifuge comprising a rotor [designed to hold reaction vessels at a tilt away from the] rotatable about an axis of rotation which holds in a fixed position at least one reaction vessel tilted away from said axis of rotation; and

b) a waste reservoir connected with a tube to said centrifuge to hold liquids expelled from said reaction vessels.

**IN THE SPECIFICATION**

Please amend the specification to add the following text at page 4, beginning at line 19 to reads as follows:

-- Fig. 6 shows a cross section of a centrifuge with a waste reservoir connected at the bottom of the centrifuge and with the rotor holding a reaction vessel at a fixed position tilted away from the axis of rotation--

### **PENDING CLAIMS**

27. (thrice Amended) An apparatus comprising:

a) a centrifuge comprising a rotor rotatable about an axis of rotation which holds in a fixed position at least one reaction vessel tilted away from said axis of rotation; and

b) a waste reservoir connected to the bottom of said centrifuge to hold liquids expelled from said reaction vessels.

28. (twice amended) An apparatus comprising:

a) a centrifuge comprising a rotor rotatable about an axis of rotation which holds in a fixed position at least one reaction vessel tilted away from said axis of rotation; and

b) a waste reservoir connected with a tube to said centrifuge to hold liquids expelled from said reaction vessels.

29. An apparatus according to claim 27 or 28 wherein said rotor comprises a plurality of holders, each holder designed to hold at least one microtiter plate.

30. An apparatus according to claim 27 or 28 further comprising a liquid distribution system.

31. An apparatus according to claim 30 wherein said liquid distribution system is integrated into the centrifuge.

32. An apparatus according to claim 27 or 28 further comprising a computer.



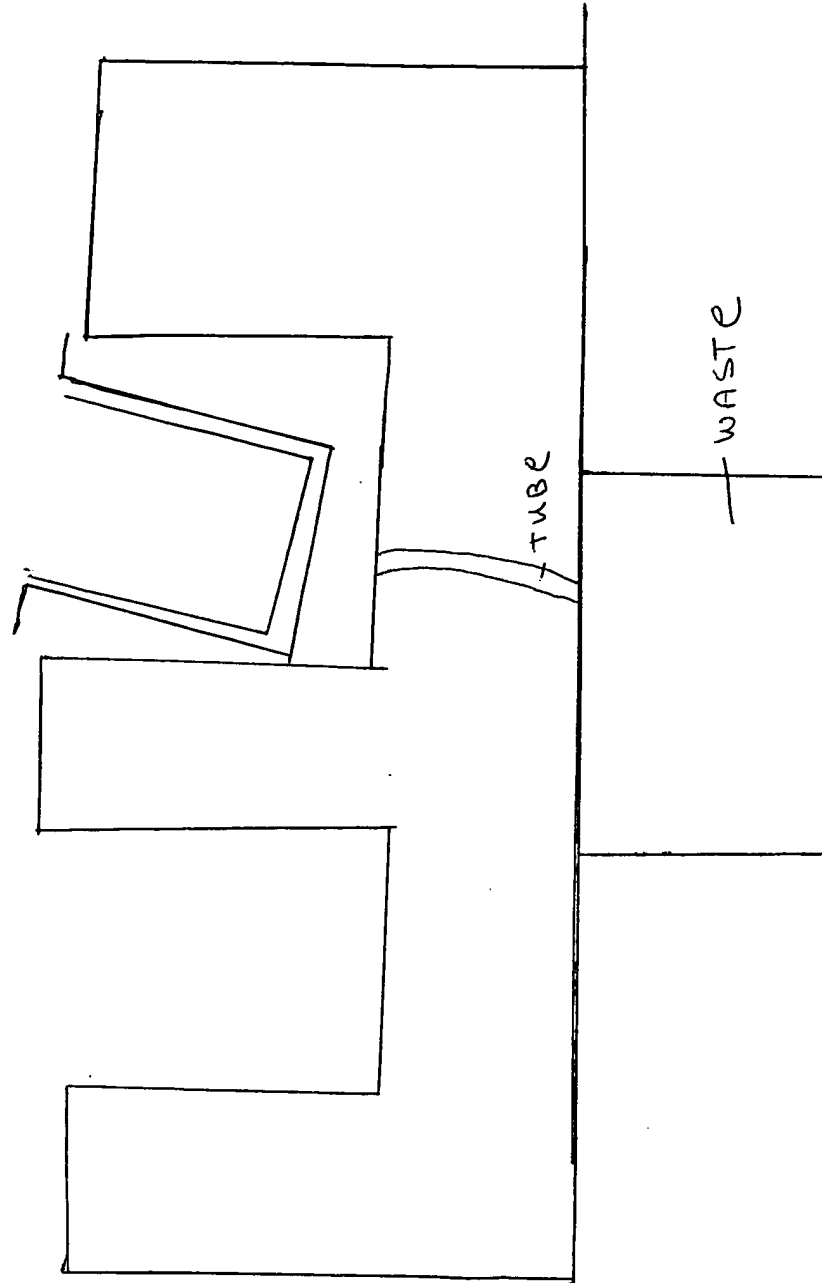


FIGURE 6